IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2326**
THIS DOCUMENT RELATES TO THE FOLLOWING CASES:	
FAYE FOREMAN **v.** **BOSTON SCIENTIFIC CORP.**	**No. 2:13-cv-15591**

PLAINTIFF FAYE FOREMAN'S COMBINED RESPONSE & SUPPORTING MEMORANDUM IN OPPOSITION TO BOSTON SCIENTIFIC'S MOTIONS FOR SUMMARY JUDGMENT

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Plaintiff Faye Foreman submits this combined response and supporting memorandum in opposition to Defendant Boston Scientific Corporation's ("BSC") motion for summary judgment on limitations and its motion for summary judgment on all claims.

In support, Plaintiff Foreman shows the Court the following:

INTRODUCTION

BSC moved for summary judgment on claims brought by Plaintiff Faye Foreman, requesting that the Court apply California law. One week earlier, it moved for summary judgment based on the California statute of limitations.

In the interest of efficiency, the Court should take note of the following:

- Plaintiff does not contest that California law governs her case.
- Plaintiff does not contest BSC's motion as to her manufacturing defect claims.
- Plaintiff does not contest BSC's motion as to strict liability for design defect.

For reasons below, the Court should deny BSC's motion with respect to limitations, as well as its motion for summary judgment on Plaintiff's claims. Unless stated otherwise, Plaintiff respectfully asks the Court to deny BSC's motion for summary judgment in all respects.

STATEMENT OF FACTS

Because certain portions of BSC's Statement of Uncontroverted Facts in both motions are questionable, Plaintiff Faye Foreman offers the following facts for a fuller picture:

1. Plaintiff Foreman commenced this action to recover injuries sustained from BSC's Advantage Fit and pleaded the following causes of action: 1) Negligence; 2) Strict Liability – Design Defect; 3) Strict Liability – Manufacturing Defect; 4) Strict Liability – Failure

to Warn; 5) Breach of Express Warranty; 6) Breach of Implied Warranty; 7) Discovery Rule, Tolling and Fraudulent Concealment; and 8) Punitive Damages.

2. Ms. Foreman resides in Oakland, California.

3. On September 2, 2009, Dr. Michael Fogarty implanted the BSC Advantage mesh device into Ms. Foreman to treat her stress urinary incontinence.

4. The implant surgery took place in Hayward, California.

5. Ms. Foreman testified that she was given information about the procedure from Dr. Michael Fogarty before her implant, and that she read the information. Ex. A (Foreman depo.) at 124:24–125:7.

6. Ms. Foreman suffered injuries related to the implanted Advantage Fit mesh, including pain with sexual intercourse, mesh erosion/extrusion, urinary incontinence, and pelvic pain.

7. Dr. Fogarty testified that prior to Ms. Foreman's procedure he read the Advantage Fit directions for use (DFU). Ex. B (Fogarty depo.) at 44:24–45:3.

8. He testified also that it is important to know the likelihood of a potential Advantage Fit risk occurring. *Id.* at 55:4–8.

9. Dr. Fogarty expected that if BSC knew that risks were more prevalent than what was known he would have wanted to be informed. *Id.* at 55:11–18.

10. He testified further that BSC never told him what the erosion rate was for the Advantage fit sling. *Id.* at 29:5–9.

11. Dr. Fogarty expected BSC to make him aware of the risks associated with the Advantage Fit procedure. *Id.* at 82:10–12.

12. Ms. Foreman testified that had she known about the likelihood of the risks of the Advantage Fit she would not have had the device implanted. Ex. A (Foreman depo.) at 266:12–15.

13. Because of the injuries she suffered from the Advantage Fit, Ms. Foreman underwent a mesh removal procedure.

14. Ms. Foreman had the Advantage Fit mesh explanted on August 12, 2010, by Dr. Xiufen Ding.

15. Ms. Foreman testified that she did not know there was anything wrong with the implant until the end of 2011. *Id.* at 27:5–17; 255:13–19.

16. Ms. Foreman filed her lawsuit directly into the MDL on June 25, 2013.

STANDARD OF REVIEW

Summary judgment is appropriate only when there is "no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c); *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 247 (1986). The Court must view all evidence in a light most favorable to Plaintiff Foreman, and resolve all reasonable doubts against BSC. *Id.* at 255. In considering a motion for summary judgment, the Court should not "weigh the evidence and determine the truth of the matter." *Id*. at 249. Rather, it should draw any permissible inference from the evidence in the light most favorable to Plaintiff. *Matsushita v. Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986).

ARGUMENT

I. PLAINTIFF FOREMAN DOES NOT CONTEST SUMMARY JUDGMENT ON "MANUFACTURING DEFECT"

In view of the Court's consistent rulings rejecting manufacturing defect claims in this litigation, Plaintiff does not intend to pursue a separate claim for "manufacturing defect" (not

manufactured in accordance with design, or departure from manufacturer's design specifications). *See Cisson*, C.A. No. 2:11-cv-00195, Dkt. No. 272 (Memorandum Opinion and Order, Bard Motion for Partial Summary Judgment) at 8; *see also Tyree v. Boston Scientific Corp.*, C.A. No. 2:12-cv-08633, Dkt. No. 446 at 5–6.

But in accordance with the Court's prior rulings, Plaintiff Foreman does intend to present evidence (1) demonstrating that BSC's manufacturing process and the raw materials used for its transvaginal mesh products resulted in product defects; and (2) supporting Plaintiff's negligence, failure to warn, and punitive damages claims. As this Court held:

> Although this process is part of the manufacturing process of the Avaulta products, it would fall within the category of a *design* defect and not a *manufacturing* defect if the process, albeit faulty, were the same for all of these products. . . . [T]he alleged inadequate pore size and use of improper polypropylene material in the Avaulta products is a design issue.

Cisson at 8.

By not contesting BSC's motion as to "manufacturing defect," Plaintiff does not forego, waive, or in any way agree that evidence relating to BSC's manufacturing process and raw materials is restricted in any respect.

II. SUMMARY JUDGMENT SHOULD BE DENIED ON PLAINTIFF FOREMAN'S CLAIM OF BREACH OF WARRANTY

BSC claims summary judgment is proper because Plaintiff did not provide the pre-claim notice required by CAL. COMM. CODE § 2607. Memo at 16. That portion of its motion should be denied.

Although Plaintiff presented no evidence on pre-claim notice, such notice need not be provided to remote manufacturers/sellers such as BSC: "The notice requirement . . . is not an appropriate one for the court to adopt in actions by injured consumers against manufacturers with

whom they have not dealt." *Greenman v. Yuba Power Prods., Inc.*, 59 Cal.2d 57, 61 (Cal. 1963). Further, the court held:

> [a]s applied to personal injuries, and notice to a remote seller, it becomes a booby-trap for the unwary. The injured consumer is seldom steeped in the business practice which justifies the rule, and at least until he has had legal advice it will not occur to him to give notice to one with whom he has had no dealings.

Id. (quoting William Prosser, *The Assault Upon the Citadel*, 69 YALE L. J. 1099, 1130 (1960)) (internal citations and footnotes omitted.)

BSC was a remote manufacturer, not the immediate seller. Limiting the notice requirement to the immediate seller is consistent both with the wording and case law, and serves to promote fairness in dealing with unsophisticated consumers. Therefore, summary judgment is improper concerning Plaintiff's breach of warranty claims.[1]

III. SUMMARY JUDGMENT SHOULD BE DENIED ON PLAINTIFF FOREMAN'S CLAIM OF FAILURE TO WARN

In California, "[a] plaintiff asserting causes of action based on a failure to warn must prove . . . [1] that no warning was provided or the warning was inadequate, [and] . . . [2] that the inadequacy or absence of the warning caused the plaintiff's injury." *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001) (*Motus I*), *aff'd sub nom. Motus v. Pfizer Inc.*, 358 F.3d 659 (9th Cir. 2004) (*Motus II*).

The adequacy of a warning is generally a question of fact. *Carlin v. Superior Court*, 56 Cal. Rptr. 2d 162, 168–69 (Cal. 1996). A warning is inadequate if it fails to "sufficiently alert the ***user*** to the possibility of danger." *Aguayo v. Crompton & Knowles Corp.*, 228 Cal. Rptr. 768, 775 (Cal. Ct. App. 1986) (emphasis added). In a medical device case such as this, the

[1] Although BSC also claims that Plaintiff's breach of warranty claim fails due to lack of privity, privity is a requirement only for breach of implied warranty. *See Evraets v. Intermedics Intraocular, Inc.*, 29 Cal. App. 4th 779, 783 (Cal. Ct. App. 1994) (Plaintiff's "claim for breach of the implied warranty of fitness fails for lack of privity. However, his breach of express warranty . . . [is] sufficient to withstand a demurrer.").

physician who implants the device is the "user." *Valentine v. Baxter Healthcare Corp.*, 81 Cal. Rptr. 2d 252, 263 (Cal. Ct. App. 1999).

California law prohibits summary judgment in "a product defect claim based on insufficient warnings" if a plaintiff adduces evidence that (1) the prescribing physician read and relied on the defendant's warnings, and (2) "stronger warnings would . . . have altered the conduct of the prescribing physician." *Motus II*, 358 F.3d at 661. That is the case here.

For example, following *Motus II*, *Hill v. Novartis Pharma. Corp.* establishes summary judgment must be denied when a plaintiff adduces any evidence that stronger warnings would have altered the conduct of the prescribing physician. No. 06-cv-00939, 2012 WL 6004161, at *4 (E.D. Cal. Nov. 30, 2012). The plaintiff's failure to warn claim in *Novartis* was premised on a drug that allegedly caused osteonecrosis. *Id.* The company argued that because her prescribing physician testified he still prescribed the drug to patients—despite knowledge that the drug could cause osteonecrosis—the plaintiff could not show that a warning defect proximately caused her injury. *Id.* But the prescribing physician "revised his patient intake form after becoming aware of the osteonecrosis risk. Previously, the form did not inform patients of the osteonecrosis risk." *Id.* And he testified further that "he would have discussed all of the items on the form with Plaintiff" had he known the risk." *Id.* Under *Motus II*, therefore, the court denied summary judgment, holding "more adequate warnings *would* have changed Plaintiff's course of medical treatment." *Id.* (emphasis in original).

BSC's citation to *Motus I* confirms the Court should deny summary judgment on Plaintiff's failure to warn claims. In both *Motus I* and *Motus II*, the court granted summary judgment on the causation issue because the prescribing physician "made unequivocal statements in a pretrial deposition demonstrating that adequate warnings would not have affected his or her

decision to prescribe a drug"; and he testified, moreover, that he did not read the package insert or PDR (a prescription drug's label) entry for the drug. *Motus I*, 196 F. Supp. 2d at 997–98. Thus, the opinions teach that a plaintiff must proffer some evidence that his or her prescribing physician read and relied on the defendant manufacturer's warnings.

Here, Plaintiff Foreman's evidence satisfies *Motus I*, *Motus II*, and *Hill*. In short, Dr. Fogarty read BSC's DFUs and would have wanted to know if BSC was aware that the risks of the Advantage Fit were more prevalent than he was aware of. When inferences are drawn from the evidence in Plaintiff's favor, summary judgment should be denied.

Dr. Fogarty testified that he reviewed the directions for use before implanting BSC's Advantage Fit product: "**Q.** Doctor, did you ever review the directions for use for the Advantage product? . . . . **A.** I'm sure I did." Ex. B (Fogarty depo.) at 44:24–45:3. He was "sure [he] reviewed [the DFU] before using that product." *Id.* at 45:12–13. Although testifying he was aware of risks associated with slings, generally, Dr. Fogarty agreed that "it's also important to know the likelihood that those risks would occur." *Id.* at 55:4–8. "**Q.** And so if [the risks] were occurring more than—than you were aware of, you would want to know that. If a manufacturer knew that it was occurring more than you thought it would be . . . **A.** Yeah, that's something I would have wanted." *Id.* at 55:11–18. Despite acknowledging the importance of knowing the likelihood of a risk occurring, Dr. Fogarty testified that he was never told an erosion rate for the Advantage Fit products: "**Q.** Were you ever told what the erosion rate was for the Advantage product? **A.** Not that I remember." *Id.* at 29:5–9. And he stressed: "I would expect that Boston Scientific would make me aware of the risks of the procedure. . . ." *Id.* at 82:10–12. Dr. Fogarty expected BSC to be candid and forthcoming about the risks associated with its products. *See id.* at 52:16–19.

Moreover, Plaintiff Foreman emphasized that she would not have had the Advantage Fit implanted had she known all of the risks. "**Q.** . . . Knowing what you know now, would you have consented to have the implant surgery. . . ? **A.** No, I wouldn't have had it." Ex. A (Foreman depo) at 266:12–15. She stressed repeatedly that had she been aware of what was going to happen, she would not have had the procedure: "If I knew . . . urgency incontinence would come back again, I wouldn't have had surgery.' *Id.* at 93:15–17. "I wouldn't have had that surgery if I had known [urinary retention] was going to happen." *Id.* at 93:20–21. "If I had known that [painful sexual intercourse]'s what it would have been, I wouldn't have had it." *Id.* at 94:7–10.

The testimony of Dr. Fogarty and Ms. Foreman raises a genuine issue of material fact on Plaintiff's claims of failure to warn. Accordingly, BSC's motion should be denied on this ground.

BSC next claims that the failure to warn claims must be dismissed as well under the "sophisticated user doctrine." Memo at 13. The sophisticated user doctrine in an affirmative defense in California. *See Johnson v. American Standard, Inc.*, 179 P.3d 905, 908 (Cal. 2008). "The focus of the defense . . . is whether the danger in question was so generally known within the trade or profession that a **manufacturer should not have been expected to provide a warning specific to the group to which plaintiff belonged**." *Id.* at 915 (emphasis supplied).

Accordingly, the doctrine is a defense used only when a plaintiff is the sophisticated user. *See id.* But in a medical device case, the physician who implants the device is the "user." *Valentine*, 81 Cal. Rptr. 2d at 263. Hence, the sophisticated user doctrine could only apply in a medical device case if the physician were the plaintiff.

BSC fails to cite any authority warranting the application of the sophisticated user doctrine in this context. None exists because logic precludes such authority. BSC cites to *Plenger v. Alza Corp.*, 13 Cal. Rptr. 2d 811 (Cal. Ct. App. 1992), but the term "sophisticated user" does not exist in the opinion. That is because the court was deciding whether a warning was adequate—not whether the sophisticated user doctrine precluded liability. Further, even assuming the doctrine did apply, BSC has offered no evidence to show that the risks associated with the Advantage Fit were "so generally known within the trade or profession," to absolve it from any duty to warn. In fact, as noted in the previous paragraphs, Dr. Fogarty testified that there were things about which he would have wanted to know.

As the sophisticated user doctrine is an affirmative defense, BSC bears the burden of proof to establish it. It has not proffered the requisite evidence to meet its burden. Accordingly, summary judgment should be denied on this ground as well.

IV. PLAINTIFF FOREMAN'S NEGLIGENCE CLAIM SURVIVES UNDER THE LEARNED INTERMEDIARY DOCTRINE

BSC argues "Plaintiffs' negligence claim also fails . . . [(1)] under the learned intermediary doctrine . . . or [(2)] as a reiteration of a design defect claim that does not exist as a matter of California law." Memo at 10. As an initial matter, the Court's disposition of the negligence–learned intermediary issue obviates BSC's position. Although BSC contends design defect claims do not exist in California, this Court has already concluded that "medical device manufacturers may be liable for design defects under the ordinary principles of negligence" in California. *See Sanchez v. Boston Scientific Corp.*, ___ F.Supp.2d ___, 2014 WL 4059214, at *8 (S.D. W.Va. Aug. 18, 2014). Thus, the Court can summarily reject BSC's argument.

Next, BSC's other argument—that the learned intermediary doctrine bars negligence claims in California—lacks merit as well. Memo at 8–9. BSC seems to argue that if Plaintiff

cannot establish proximate cause on her failure to warn claim, every other claim fails as a matter of law. However, BSC cites no authority for its bold position. That is because negligence theories in California survive summary judgment on failure to warn claims under the learned intermediary doctrine. *See, e.g.*, *Tucker v. Wright Med. Tech., Inc.*, No. 11-cv-03086, 2013 WL 1149717, at *10, 16 (N.D. Cal. March 19, 2013); *Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1487 n.15, 81 Cal. Rptr. 2d 252 (Cal. Ct. App.1999).

The learned intermediary doctrine does not bar all causes of action when a court grants summary judgment on failure to warn due to lack of causation evidence. *Tucker*, 2013 WL 1149717, at *1 (granting summary judgment on plaintiff's strict liability and negligent failure to warn claims because there was no evidence the implanting physician read the defendant's warning; **but denying defendant's motion for summary judgment on plaintiff's negligence claim under California law**); *Saavedra v. Eli Lily & Co.*, No. 2:12-cv-9366, 2013 WL 6345442, at *4 (C.D. Cal. Feb. 26, 2013) (holding California's learned intermediary doctrine does not "bar *every* cause of action by a consumer against a drug manufacturer, *even if the manufacturer had inadequately warned physicians*.") (italics in original).

Tucker illustrates that California's learned intermediary doctrine does not bar all claims against a medical device manufacturer. The plaintiff in *Tucker* brought a products liability action against a hip implant manufacturer after sustaining injuries from the implantation of a defective hip replacement. *Id.* at *1–2. But the plaintiff presented no evidence that her physician read the defendant's warnings. *Id.* at *16. Applying *Motus I* and *Motus II*, the court granted summary judgment on strict liability/negligent failure to warn claims, since there was no evidence that the defective warnings caused the plaintiff's injuries. *Id.* But the court denied summary judgment on the negligent design claim. *Id.* at *10. *Tucker* teaches that a plaintiff's

negligence-based claims survive summary judgment even when the learned intermediary doctrine bars his or her strict liability/negligent failure to warn claims.

Therefore, even if the Court determines the learned intermediary doctrine bars Plaintiff's failure to warn claims, the following negligence-based claims—pleaded in Plaintiffs' Short Form and Master Complaints—survive under California's substantive law:

- **Negligence**. *Friedman v. Merck & Co.*, 107 Cal. App. 4th 454, 463, 131 Cal. Rptr. 2d 885, 890 (2003);
- **Negligent Design**. *Chavez v. Glock, Inc.*, 207 Cal.App.4th 1283, 1305, 144 Cal. Rptr. 3d 326 (Cal. Ct. App. 2012);
- **Negligent Failure to Test**. *Post v. Alameda Amusement Co.*, 117 Cal. App. 2d 588, 590, 256 P.2d 580 (Cal. Ct. App. 1953);
- **Negligent Undertaking of the Duty to Train**. *Artiglio v. Corning Inc.*, 957 P.2d 1313, 1318 (Cal. 1998); *Paz v. State of California*, 994 P.2d 975, 981 (Cal. 2000);[2]
- **Negligent Misrepresentation**. *Apollo Capital Fund, LLC v. Roth Capital Partners, LLC*, 158 Cal. App. 4th 226, 70 Cal. Rptr. 3d 199 (Cal. Ct. App. 2007).

Because BSC did not move for summary judgment on Plaintiff's negligence-based cause of action (other than to simply claim that the learned intermediary and strict liability design defect theories bar recovery), judgment on those claims is improper. In addition, summary judgment is improper on Plaintiff's negligence-based claims because California's learned intermediary doctrine does not bar those claims. The Court should deny BSC's motion for summary judgment.

[2] BSC states that there is no duty to train on "basic operations." There can be no question that transvaginal mesh placement is not a "basic operation." Indeed, BSC's own internal documents from 2011 reveal that training is paramount: "Obtain specialized training for each mesh placement technique, and be aware of its risks." Ex. F BSCM06100068366. "Surgeons should focus on consent, selection and adequate training." *See* Ex. F BSCM06100068370. "Better surgeon training." *See* Ex. F BSCM06100068372.

V. THE EVIDENCE RAISES QUESTIONS ON ADVANTAGE FIT'S CAUSATION OF PLAINTIFF FOREMAN'S INJURIES

BSC insists Ms. Foreman's claims all fail because "Plaintiff cannot show that the specific defect complained about was the cause of her injuries." Memo at 15. But Plaintiff can present evidence that the Advantage Fit caused her injuries.

In California, plaintiffs must prove general causation and specific causation in a medical device case. *Monroe v. Zimmer U.S. Inc.*, 766 F. Supp. 2d 1012, 1028 (E.D. Cal. 2011). To establish general causation, plaintiffs must show "that the product is capable of causing the harm." *Id.* To establish specific causation, they must show "that the product caused the harm in this specific case." *Id.* Plaintiff Foreman has evidence of both.

A. Plaintiff Presents Evidence of General and Specific Causation

Following implantation of the Advantage Fit, expert evidence demonstrates that Ms. Foreman suffered mesh erosion/extrusion, infections, pain, pain with intercourse, and urinary complications. *See* Ex. C (Rosenzweig report at 8). Plaintiff's general causation expert, Dr. Bruce Rosenzweig, opined that the Advantage is capable of causing foreign body reaction, enhanced inflammatory response, excessive scarring, erosions, chronic pelvic pain, recurrence, worsening incontinence, chronic dyspareunia, wound infection, rejection of the mesh, sexual dysfunction, the need for additional surgeries, and urinary complications. *Id.* (Rosenzweig general report) at 14, 19, 21–23.

Plaintiff has therefore shown general causation, as the foregoing opinions are evidence "that the [Advantage Fit] [is] capable of causing the harm." *See Monroe*, 766 F. Supp. 2d at 1028. Dr. Rosenzweig also opined that the "contraction/shrinkage of the Advantage caused Ms. Foreman's recurrent SUI, pain with intercourse, urine retention, and incomplete bladder emptying." Ex. C (Rosenzweig report) at 9. She also demonstrates specific causation because

Dr. Rosenzweig's opinion is evidence "that the [Advantage] caused the harm in this specific case." *Monroe*, 766 F. Supp. 2d at 1028. The Court should deny BSC's motion because the foregoing evidence suffices to show causation in a California medical device case. *See id.*

B. Plaintiff Presents Evidence of Design Defect

In the context of medical devices, design defects must be pursued under a negligence theory in California. *Armstrong v. Optical Radiation Corp.*, 50 Cal. App. 4th 580, 595 (1996); *see also Scott v. C.R. Bard, Inc.*, 231 Cal. App. 4th 763, 774 (2014) (finding that "being immune from strict liability does not in itself bar a negligence claim"). A product is defective if its design embodies "excessive preventable danger unless 'the benefits of the . . . design outweigh the risk of danger inherent in such design.'" *Morson v. Superior Court*, 90 Cal. App. 4th 775, 785 (2001) (quoting *Barker v. Lull Eng'g Co.*, 20 Cal.3d 413, 430, 432 (1978) (alteration in original) (internal citations omitted)).

A design defect inquiry involves "technical issues of feasibility, cost, practicality, risk, and benefit which are 'impossible' to avoid." *Id.* (internal citations omitted). "In such cases, the jury must consider the manufacturer's evidence of competing design considerations, and the issue of design defect cannot fairly be resolved by standardless reference to the expectations of an ordinary consumer." *Id.* (internal citations and quotations omitted). "[E]xpert testimony will be essential in the medical and manufacturing fields to assist the finder of fact in understanding the relevant sequence of events and the nature of the alleged injuries." *Id.* at 779.

Here, Plaintiff utilized the expert testimony of Dr. Rosenzweig as evidence showing the Advantage Fit was defectively designed. For example, he opined that the "polypropylene mesh used in Boston Scientific's Advantage, Advantage Fit and Lynx ("Advantage Mesh") products is not suitable for its intended application as a permanent prosthetic implant. . . ." Ex. C

(Rosenzweig general report) at 10. He opined additionally that "[t]he weave of the Advantage meshes produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them." *Id.* at 19. Finally, Dr. Rosenzweig offered his opinion that "based on [his] training, experience and extensive review of the literature and Boston Scientific's internal documents, the benefits of the . . . Advantage Fit . . . are outweighed by the severe, debilitating and life changing complications associated with the medical devices." *Id.* at 36. He testified further that traditional surgeries, like the Burch and pubovaginal slings, are not associated with the frequency or extent of the life-changing complications associated with the Advantage Fit. *Id.*

Another of Plaintiff's experts, Dr. Jerry Blaivas, opined as well that the design of the Advantage Fit was defective:

> [T]he Boston Scientific Advantage Fit Transvaginal Mid-Urethral Sling System (Advantage Fit) . . . polypropylene slings for the treatment of stress urinary incontinence are too dangerous in their current design because they cause . . . serious, sometimes lifestyle altering complications. . . ."

Ex. D (Blaivas general report) at 3. Dr. Blaivas went on to opine that pubovaginal slings "using autologous fascia are a safer alternative to synthetic slings," and that pubovaginal slings are as effective as synthetic slings, including the Advantage Fit. *Id.* at 4.

Plaintiff has proffered the requisite expert testimony to raise genuine issues of material fact regarding the defective design of the Advantage Fit. Accordingly, BSC's motion for summary judgment should be denied on this ground too.

VI. PLAINTIFF FOREMAN'S CLAIMS ARE NOT TIME-BARRED

In an effort to convince the Court that Plaintiff's claims are barred by limitations, BSC presents a skewed portrayal of her medical history, the timing of her knowledge of critical facts, and her injuries. The Court will see that Plaintiff Foreman timely filed her lawsuit in June 2013,

after finally learning at the end of 2011 of the "wrongful cause" of her injuries. As BSC cannot establish that her claims are time-barred, its motion should be denied.

A. California Statute of Limitations

Plaintiff agrees that the two-year statute of limitations under CAL. CODE CIV. P. 335.1 applies in this case. The statute requires that civil actions be brought within two years for injury to an individual caused by the wrongful act of another. *Id*. Underlying policies include protecting defendants from stale claims and stimulating plaintiffs to pursue their claims. *See Fox v. Ethicon Endo-Surgery, Inc.*, 110 P.3d 914, 919 (Cal. 2005). But "[a] countervailing factor . . . is the policy favoring disposition of cases on the merits rather than on procedural grounds." *Id.* at 920. Limitations begin to run when a cause of action accrues—generally when the claim is "complete with all its elements." *Id.*

An exception is California's adoption of the "'discovery rule,' which postpones accrual of a cause of action until the plaintiff discovers, or has reason to discover, the cause of action." *Id.* (citing *Nogart v. Upjohn Co.*, 981 P.2d 79 (Cal. 1999)). A plaintiff's "ignorance of wrongdoing involving a product's defect will usually delay accrual because such wrongdoing is essential to [a product liability] cause of action." *Id.* at 924. "It would be contrary to public policy to require plaintiffs to file a lawsuit 'at a time when the evidence available to them failed to indicate a cause of action.'" *Id.* at 925 (quoting *Leaf v. City of San Mateo*, 104 Cal. App. 3d 398, 408 (1st Dist. 1980)).

B. Plaintiff Did Not Discover the Wrongdoing Until Seeing Ads on Television

BSC argues primarily that Ms. Foreman's Advantage Fit removal surgery provided her with knowledge to determine wrongdoing, sufficient to file her lawsuit against BSC. SOL Memo at 8–9. That is not correct. As the California Supreme Court held in *Fox*, evidence of

wrongdoing is essential to a products liability claim. 110 P.3d at 925. Ms. Foreman had no such knowledge at the time of her removal surgery.

Ms. Foreman's Plaintiff Fact Sheet (PFS) indicates that she first attributed her injury of **mesh erosion/exposure** to the Advantage Fit in 2010, when she had her removal surgery. Obviously, mesh erosion would be caused by mesh. Ex. E (PFS) at 5. But at that time she had absolutely no knowledge of BSC's wrongdoing. In fact, Ms. Foreman testified that she did not know of any wrongdoing until she saw a television ad:

> I knew I had an implant. I also knew that I had had it removed, but I didn't know there was anything wrong with an implant. I wanted to get some information and see if this was something I wanted to do.

Ex. A (Foreman depo.) at 28:14–18. And she continued in the same vein, responding that she did not attribute her incontinence to the BSC device:

> Up until I saw the ads, I thought it was just my body. Okay. Now, that I'm see[ing] the ads, I guess it's a possibility. I'm not a doctor. I'm not—I don't—I didn't make the device.

Id. at 252:4–9. "**Q.** So at that time [2010], you suspected there was something wrong, but you didn't know it was caused by the mesh? **A.** I did not know until the end of 2011 that there was anything going on with the mesh that would cause me injury." *Id.* at 255:13–19. "**Q.** When you said the end of 2011, can you give me a date or a month you're referring to? **A.** Probably around Thanksgiving 2011, towards Christmas. **Q.** So your best estimate . . . [was] sometime between Thanksgiving and Christmas 2011, would be end of November, end of December time period? **A.** Yes." *Id.* at 265:23–266:8.

Further, Ms. Foreman's delayed discovery of her mesh-related complications is reasonable because no one ever told her the Advantage Fit was defective: "**Q.** Has any healthcare provider told you that your symptoms following the mesh implant were due to the mesh implant?

A. No. No. No one has told—they didn't tell me that. Like I said, I just thought my body rejected it." *Id.* at 231:19–24.

In sum, the Court should deny BSC's limitations motion because Ms. Foreman filed her complaint only after seeing lawyer advertisements for transvaginal mesh within two years of discovering her claim. Ms. Foreman's delayed discovery was reasonable because no physician had ever told her that her injuries were attributable to the defective Advantage Fit. Therefore, the Court should deny BSC's motion for summary judgment on limitations.

CONCLUSION

BSC has failed to carry its summary judgment burdens as to its motion on Plaintiff's claims and on statute of limitations. Therefore, Plaintiff respectfully requests that the Court deny summary judgment on all contested portions of BSC's motions.

This 16th day of February, 2015.

By: /s/ Karen Beyea-Schroeder

Karen Beyea-Schroeder (TX Bar No. 24054324)
G. Sean Jez (TX Bar No. 00796829)
FLEMING, NOLEN & JEZ, L.L.P.
2800 Post Oak Blvd., Suite 4000
Houston, Texas 77056-6109
Tel: 713-621-7944
Fax: 713-621-9638
karen_beyea-schroeder@fleming-law.com
sean_jez@fleming-law.com

ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

I hereby certify that on February 16, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

s/ Karen Beyea-Schroeder
Karen Beyea-Schroeder